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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,237	02/08/2001	Frederik Coenraad Botha	P-6149	2105

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EXAMINER
KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/779,237	BOTHA ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The rejection of Claims 1-6, 8-15, and 17-30 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments.

The rejection of Claims 1-4, 6, 8, and 12 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments.

The rejection of Claims 1-4, 6, 8-14, and 17-30 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments.

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: Claim 7 has not been amended to refer to a sequence identifier.

> § 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;
>
> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

Claim Rejections - 35 USC § 112

Claim 1-6, 8-15, and 17-30 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of applicant's amendments. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/23/02. Applicants arguments filed 12/25/02 have been considered but are not deemed persuasive.

Applicant asserts that the method of altering sucrose levels in sugarcane by regulating the activity of the PFP enzyme would not be obvious to one of skill in the art, that amending Claim 3 to delete references to variants or portions of SEQ ID NO: 1 or 2 and sequences that hybridize to SEQ ID NO: 1 and 2 will overcome the Examiner's objections, that the references to "untranslatable form" has not been deleted since it is known how to make sequences untranslatable, (response page 3) and that the sequences in the specification should serve as an adequate description of the complement thereof (response page 4).

Applicant has not described portions or fragments, other than SEQ ID NO: 1, or untranslatable variant forms of either SEQ ID NO: 1 or 2 to the extent sufficient to adequately describe the broadly claimed genus of isolated nucleotide sequences set forth in the claims.

Applicant has not described all the possible or a representative number of the broadly claimed genus of sequences comprising portions, fragments, or untranslatable forms of SEQ ID NO: 1 or 2. Applicant has provided no guidance in the specification other than to suggest modification of SEQ ID NO: 1 or 2 to eliminate a translation initation codon or to introduce an

in-frame termination codon somewhere downstream of the initation codon, which because it is not clear where that is to be done, does not eliminate the possibility of functional proteins translated from one of those many broadly claimed variants. Untranslatable forms of SEQ ID NO: 1 or 2 would comprise the antisense versions as well since it is known that antisense in almost all cases is not capable of translation of a functional peptide and is considered. Furthermore, an untranslatable form of SEQ ID NO: 1 or 2, when one contemplates the possible permutations, is so broad as to read upon other claimed sequences of a regulatory nature such as promoters. Further, the Examiner believes that it is clearer to the nature of the invention described in Claims 1 and 2 to assert "regulation of the activity of a PFP enzyme subunit encoded by SEQ ID NO: 2".

Claims 1-6, 8-15, and 17-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, is enabling only for claims limited to the isolated sugarcane PFP nucleotide sequences of SEQ ID NO: 1 and SEQ ID NO: 2, a method of down regulating the total activity of the PFP enzyme in a plant by transformation with a plant expression vector comprising either a sense or an antisense version of SEQ ID NO: 2 encoding the PFP-β subunit from sugarcane such that sucrose content is increased. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/23/02. Applicants arguments filed 12/25/02 have been considered but are not deemed persuasive.

Applicant asserts that methods of upregulating or down regulating the enzyme activity would be obvious to a person skilled in the art and that the invention is that sucrose content can be regulated by regulation enzyme activity; that homology dependent silencing is dependent upon high levels of homology (sequence identity) to the DNA and RNA of the invention (response page 5); and that Applicants have failed to see the relevance of the "unpredictability of antisense inhibition" argument because the methods of achieving said down regulation by antisense are easily prepared. Further, Applicant admits that it is impossible to predict how much inhibition will be obtained before a plant is transformed (response page 6).

The unpredictability of Applicant's admission is increased when the sequences of the claimed methods and plants comprising said sequences require undue experimentation to isolate and identify other non-exemplified PFP nucleic acids, or non-exemplified portions thereof, or non-exemplified untranslatable forms that are effective in the claimed methods.

Claims 5, 15, and 16 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/23/02. Applicants arguments filed 12/25/02 have been considered but are not deemed persuasive.

Applicant asserts that they will supply an affidavit that the vectors of the invention will be made available to the public for the amount of time required (response page 5). The rejection is maintained until said affidavit is received by the Office.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
February 13, 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600